K010878

APR 1 8 2001

510(k) Summary
Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045
Telephone Number:	(310) 645-8200
Facsimile Number:	(310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director, Clinical Affairs
Date of Preparation:	April 13, 2001
Device Name:	
Trade:	IMMULITE 2000 Herpes I&II IgG
Catalog Number:	L2KHS2 (200 tests); L2KHS6 (600 tests)
Common:	Reagent system for the determination of Herpes I & II IgG antibodies in human serum.
Classification:	Class III device (866.3305)
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Establishment Registration #:	DPC's Registration # is 2017183
Substantially Equivalent Predicate Device:	IMMULITE Herpes I&II IgG (K950670)

Description of Device: IMMULITE 2000 Herpes I&II IgG is a clinical device for use with the IMMULITE 2000 Automated Immunoassay Analyzer

Intended Use of the Device: IMMULITE Herpes I&II IgG is designed for the qualitative detection of IgG antibodies to herpes simplex virus (HSV) types I and II in human serum. It is intended strictly for *in vitro* diagnostic use as an aid in the determination of serological status to HSV I&II.

Summary and Explanation of the Device:

Herpes simplex virus (HSV) is an ancient and ubiquitous virus, known to cause acute and recurrent infections in humans. The virus enters the mucous membranes (ocular, genital, or oral) and replicates locally and may enter the sensory root ganglion, resulting in latent, recurrent infections. Infection of neonates during passage through the birth canal may result in neurological damage and death.

In the 1960s it was recognized that HSV consisted of two distinct types, HSV-I and HSV-II. HSV-I is considered to be primarily associated with ocular and oral infection, while HSV-II is considered to be a genital infection. However, HSV types I and II share several common antigens, and the use of specific monoclonal antibodies or restriction endonuclease mapping is required to type individual strains.

Infections with HSV type I or type II can differ in their clinical manifestations and severity. The immune response of the host can play an important role in controlling the severity of primary or reactivated infections. Those at highest risk for severe infections are neonates, who are infected during delivery, and immunocompromised patients.

While isolation of the virus in tissue culture is recommended for the diagnosis of active infections, serological testing can provide valuable information in the management of at-risk populations, such as pregnant women.

Performance Equivalence - Technology Comparison:

Diagnostic Products Corporation (DPC) asserts that **IMMULITE® 2000 Herpes I&II IgG** is substantially equivalent to the **IMMULITE® Herpes I&II IgG** kit marketed by DPC.

Each product is designed for the qualitative measurement of IgG antibodies to herpes simplex virus (HSV) types I and II in human serum. Each product is intended strictly for *in vitro* diagnostic use as an aid in the determination of serological status to HSV I & II.

IMMULITE® 2000 Herpes I&II IgG is a solid-phase, two-step, chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead, is coated with partially purified HSV I and II viral antigen.

The patient sample and a protein-based buffer are simultaneously introduced into the Reaction Tube, and incubated for approximately 30 minutes at 37 °C with intermittent agitation. During this time, herpes I and II IgG in the sample binds to the HSV I and II antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgG antibody is introduced, and the Reaction Tube is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Reaction Tube is incubated for an additional 5 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple reading. The bound complex - and thus the photon output, as measured by the luminometer - is proportional to the presence of HSV I and II IgG in the sample. A qualitative result is then obtained by comparing the patient result to an established Cutoff.

IMMULITE® Herpes I&II IgG is a solid-phase, two-step, chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with partially purified HSV I and II viral antigen.

Prediluted patient sample (1-in-21 dilution) and a protein-based buffer are simultaneously introduced into the Test Unit, and incubated for approximately 30 minutes at 37 °C with intermittent agitation. During this time, herpes I and II IgG in the sample binds to the HSV I and II antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgG antibody is introduced, and the Test Unit is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a

centrifugal wash. Substrate is then added, and the Test Unit is incubated for an additional 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple reading. The bound complex - and thus the photon output, as measured by the luminometer - is proportional to the presence of HSV I and II IgG in the sample. A qualitative result is then obtained by comparing the patient result to an established Cutoff.

Performance Equivalence - Method Comparison:

The performance of the **IMMULITE 2000 Herpes I&II IgG** procedure was compared to the commercially available **IMMULITE Herpes I&II IgG.** A summary of the results is shown in the table below.

IMMULITE 2000 Herpes I&II IgG

	IMMULITE 2000		
IMMULITE	**Positive**	**Indeterminate**	**Negative**
Positive	167	0	0
Indeterminate	0	2	0
Negative	0	2	56

Agreement: 99.1%

Conclusion:

The conclusions drawn from the clinical and nonclinical studies demonstrate that the device is safe, effective, and performs as well as, or better, than the current legally marketed devices.

Edward M. Levine

Edward M. Levine, Ph.D.
Director, Clinical Affairs

4/13/01

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 8 2001

Edward M. Levine, Ph.D.
Director, Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045

Re: K010878
Trade Name: IMMULITE 2000 Herpes I & II IgG
Regulation Number: CFR § 866.3305
Regulatory Class: III
Product Code: LGC
Dated: March 16, 2001
Received: March 19, 2001

Dear Dr. Levine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): _____
Device Name: IMMULITE® 2000 Herpes I&II IgG

Indications For Use: For in vitro use with the IMMULITE 2000 Analyzer – for the qualitative detection of IgG antibodies to herpes simplex virus (HSV) types I and II in human serum, as an aid in determination of serological status to HSV I&II.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010878

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use

(Optional Format 1-2-96)